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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/007,047	12/06/2001	Theodora Ross	UM-06692	6232

7590 01/26/2006

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EXAMINER

FETTEROLF, BRANDON J

ART UNIT PAPER NUMBER

1642

DATE MAILED: 01/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/007,047	Applicant(s) ROSS ET AL.	
	Examiner Brandon J. Fetterolf, PhD	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 October 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9, 12-16, 23-27, 29, 36 and 84-95 is/are pending in the application.
- 4a) Of the above claim(s) 84-86 and 91-93 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 24-27, 29, 36 and 95 is/are allowed.
- 6) ☒ Claim(s) 9, 12-18, 23 and 94 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

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Ross et al.

Response to the Amendment

The Amendment filed on 10/28/2005 in response to the previous Non-Final Office Action (07/27/2005) is acknowledged and has been entered.

Claims 9, 12-16, 18, 23-27, 29, 36 and 84-95 are currently pending.

Claims 84-86 and 91-93 are withdrawn from consideration as being drawn to non-elected inventions.

Claims 9, 12-18, 23-27, 29, 36, 87-90 and 94-95 are currently under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Rejections Maintained:

Claims 9, 12-18, 23 **remain** and **new claim 94** is rejected under 35 U.S.C. 102(e) as being anticipated by Chen et al. (US 6,794,501, 05/2001).

Chen et al. teach (column 6, lines 5-13) a method of diagnosing colon cancer in a subject comprising obtaining a biological sample from a subject and determining the expression of at least two colon cancer-associated nucleic acid molecules in a sample, wherein the expression is diagnostic of colon cancer. With regards to the nucleic acid, the patent teaches a nucleic acid molecule which has 56.9% sequence similarity from nucleotides 619 to 3118 of the presently claimed nucleic acid of SEQ ID NO: 1 (see attached sequence comparison). With regards to the sample, Chen et al. teach (column 6, lines 21-24) that the sample includes, but is not limited to, colorectal tissue and/or blood. With regards to detecting, the patent teaches (column 11, lines 29-70 and column 23, lines 45+) the detecting the nucleic acid comprises detecting RNA expression by using direct RNA amplification, reverse transcription of RNA to cDNA or by nucleic acid microarray technology. Chen et al. further teach that the detection of the nucleic acid may comprise exposing a probe with a nucleic acid sequence that perfectly matches the target sequence. Furthermore, the patent teaches (page 6, lines 30+) a method of providing a prognosis to a subject comprising determining the expression

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level of the nucleic acid. Thus, while Chen et al. does not teach that the probe is “complementary”, the claimed functional limitation would be an inherent property of the referenced method since the specification discusses (page 21, lines 1-9) that the term complementary is used in reference to nucleic acid bases which are matched according to the base pairing rules. Thus, it does not appear that the claim language or limitation results in a manipulative difference in the method steps when compared to the prior art disclosure. See Bristol-Myers Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508 (CAFC 2001).

In response to this rejection, Applicants contend that claims 9 and 24 have been amended to specify probes for detection of a HIP1 nucleic acid consisting of SEQ ID NO: 1. Applicants further submit that Chen does not teach a HIP1 nucleic acid consisting of the nucleic acid of SEQ ID NO: 1. As such, Applicants assert that Chen does not teach all of the claimed elements of the claims as required for rejection under USC 102.

These arguments have been considered, but are not found persuasive.

In response to Applicants argument that Chen does not teach a HIP1 nucleic acid consisting of the nucleic acid of SEQ ID NO: 1, the Examiner recognizes that Chen does not specifically recite a HIP1 nucleic acid consisting of the nucleic acid of SEQ ID NO: 1. However, the claims are drawn to a method of detecting colon or prostate cancer comprising detecting the presence or absence of HIP1 in a sample with a nucleic acid probe configured to hybridize to a HIP1 sequence consisting of the nucleic acid sequence of SEQID NO:1. In this case, the claims do not appear to specifically recite what nucleotides the nucleic acid probe is configured to hybridize to or any type of length limitation for the nucleic acid probe. Thus, a probe consisting of nucleotides 2089 to 2116 of Chen’s colon associated nucleic acid would inherently hybridize to nucleotides 2680 to 2708 of the nucleic acid of SEQ ID NO: 1; and therefore, be used for the diagnosis of colon cancer by detecting either the nucleic acid disclosed by Chen or the nucleic acid sequence of SEQ ID NO: 1.

Claims 24-27, 29, 36, 87-90 and 95 appear to be free of the prior art and are in condition for allowance.

All other rejections and/or objections are withdrawn in view of applicant’s amendments and arguments there to.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon J. Fetterolf, PhD whose telephone number is (571)-272-2919. The examiner can normally be reached on Monday through Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeff Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Brandon J Fetterolf, PhD
Examiner
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BF


JEFFREY SIEW
SUPERVISORY PATENT EXAMINER
1/23/06